REMARKS

The Official Action dated February 25, 2004 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, the specification is amended to correct typographical errors at page 7, to clarify the SEQ ID NOS at pages 8 and 9 and to include SEQ ID NOS in Tables 2-5 at pages 17-20. Additionally, claims 1-8 and 13-24 have been cancelled and claims 25-46 are added. Claims 25-44 contain limitations from previous claims 1, 3, 15, 17, 19, 4-8, 21-24, 2, 13, 14, 16, 18, 20, 1 and 2, respectively, and from the specification. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

The Examiner's reconsideration of the restriction requirement and examination of claims 1-8 and 13-20 in the present application is acknowledged and appreciated. As claims 25-34 and 39-46 are believed to correspond with the previously elected claims, it is believed that examination should continue with these claims. Additionally, as claims 35-38 contain subject matter from previous claims 21-24, it is believed that these claims should be withdrawn as being directed to a nonelected invention. However, as claims 21-24 depend from claim 25, Applicants request rejoinder of claims 35-38 upon the allowance of linking claim 25.

Claims 1-3 and 13 were objected to for missing the article "A" while claims 4, 5, 14 and 15 were objected to for missing the article "The". It is believed that claims 25-46 presented herein contain the appropriate articles.

The disclosure was objected to for failing to comply with the requirements of 37 C.F.R. 1.821(d), as the Examiner asserted that sequence identification numbering was

required for pages 17-20. Accordingly, the tables at pages 17-20 have been amended to recite the sequence identification numbering.

The disclosure was objected to as containing certain informalities. The Examiner questioned the Amendment filed June 11, 2002 and the references therein to the sequence identification numbers and to the table titles at pages 17-20, and noted a typographical error on page 7. It is believed that the amendments to the specification set forth herein overcome the informalities noted by the Examiner.

Claims 1-8 and 13-20 were rejected under 35 U.S.C. §112, first paragraph, on the basis that the specification does not enable and does not provide a written description of *any* group 2 allergen specific human IgE-Fabs having *any* combination of the amino acid sequences or *any* "essentially homologous variant thereof" as set forth in claims 1, 4 and 5, or *any* group 2 allergen specific human IgE-Fabs having *any* combination of nucleic acid sequences or *any* "essentially homologous variant thereof" as set forth in claims 2, 13 and 14. The Examiner admitted that the specification is enabling for and provides a written description for three Phl p2 specific human IgE Fab fragments consisting of a heavy chain and a light chain of SEQ ID NO: 7 and SEQ ID NO:10, SEQ ID NO: 8 and SEQ ID NO: 11, or SEQ ID NO: 9 and SEQ ID NO: 12, and a Phl p2 specific antibody comprising the variable region comprising a heavy chain and a light chain, and a human IgE wherein the heavy/light chains are of the aforementioned combinations.

However, Applicants submit that claims 25-46 are both enabled and fully described by the present specification, in accordance with the requirements of 35 U.S.C. §112, first paragraph. Accordingly, these rejections are traversed and reconsideration is respectfully requested.

More particularly, independent claim 25 is directed to a group 2 allergen specific human IgE Fab having a heavy chain consisting of an amino acid sequence as shown in SEQ

ID NO: 7, SEQ ID NO: 8, or SEQ ID NO: 9, and/or a light chain consisting of an amino acid sequence as shown in SEQ ID NO: 10, SEQ ID NO: 11, or SEQ ID NO: 12. Independent claim 39 is directed to a group 2 allergen specific human IgE Fab having a heavy chain encoded by a nucleic acid sequence as shown in SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO: 3, and/or a light chain encoded by the nucleic acid as shown in SEQ ID NO: 4, SEQ ID NO: 5, or SEQ ID NO: 6. Independent claim 45 is directed to a group 2 allergen specific human IgE Fab having a heavy chain consisting of an amino acid sequence as shown in SEQ ID NO: 7, SEQ ID NO: 8, or SEQ ID NO: 9, and a light chain consisting of an amino acid sequence as shown in SEQ ID NO: 10, SEQ ID NO: 11, or SEQ ID NO: 12, respectively. Finally, independent claim 46 is directed to a group 2 allergen specific human IgE Fab having a heavy chain encoded by a nucleic acid sequence as shown in SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO: 3, and a light chain encoded by the nucleic acid as shown in SEQ ID NO: 4, SEQ ID NO: 5, or SEQ ID NO: 6, respectively.

Thus, the claims do not employ the phrase "essentially homologous variant thereof." Moreover, while claims 25 and 39 encompass various combinations of heavy and light chains, such combinations are within the description of the invention set forth in the specification at page 3, lines 1-12, which do not require particular combinations of heavy and light chain sequences. Further, claims 45 and 46 are directed to particular combinations of heavy and light chains, and the Fabs and IgG, diagnostic reagents, kits and vaccines employing the same are fully exemplified in the detailed description of the present application. Thus, the present claims are both enabled and fully described by the present specification, in accordance with the requirements of 35 U.S.C. §112, first paragraph, whereby the rejection has been overcome. Reconsideration is respectfully requested.

Claims 1, 2, 4-6, 8, 14, 16 and 20 were rejected under 35 U.S.C. §102 as being anticipated by Steinberger et al, *J. Biol. Chem.*, 271(18):10967-72 (1996). The Examiner

referred to Fig. 5B with respect to present SEQ ID NO: 10 and Fig. 4 with respect to present SEQ ID NO: 7. The Examiner asserted that the term "essentially homologous variant" includes the sequences disclosed by Steinberger et al.

However, as set forth in detail below, Applicants submit that the Fabs, diagnostic reagents and kits defined by the present claims are not anticipated by and are patentably distinguishable from Steinberger et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

As noted above, independent claims 25, 39, 45 and 46 are directed to group 2 allergen specific human IgE Fabs. Claim 25 defines the Fab as having a heavy chain consisting of an amino acid sequence as shown in SEQ ID NO: 7, SEQ ID NO: 8, or SEQ ID NO: 9, and/or a light chain consisting of an amino acid sequence as shown in SEQ ID NO: 10, SEQ ID NO: 11, or SEQ ID NO: 12. Claim 39 specifies the Fab as having a heavy chain encoded by a nucleic acid sequence as shown in SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO: 3, and/or a light chain encoded by the nucleic acid as shown in SEQ ID NO: 4, SEQ ID NO: 5, or SEQ ID NO: 6. Claim 45 defines the Fab as having a heavy chain consisting of an amino acid sequence as shown in SEQ ID NO: 7, SEQ ID NO: 8, or SEQ ID NO: 9, and a light chain consisting of an amino acid sequence as shown in SEQ ID NO: 10, SEQ ID NO: 11, or SEQ ID NO: 12, respectively. Claim 46 specifies the Fab as having a heavy chain encoded by a nucleic acid sequence as shown in SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO: 3, and a light chain encoded by the nucleic acid as shown in SEQ ID NO: 4, SEQ ID NO: 5, or SEQ ID NO: 6, respectively.

A comparison of the sequences disclosed by Steinberger et al, including those at page 10970, Figs. 4 and 5B, and the sequences of claims 25, 39, 45 and 46, including SEQ ID NOS: 7 and 10, according to the present invention, demonstrates that Steinberger et al fail to

disclose the sequences of the present claims and therefore that Steinberger et al fail to disclose the claimed group 2 allergen specific human IgE Fabs.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In re Robertson*, 49 U.S.P.Q.2d 1949, 1950 (Fed Cir. 1999). In view of the deficiencies in the teachings of Steinberger et al with respect to the claimed sequences and Fabs, Steinberger et al do not anticipate the present claims under 35 U.S.C. §102. Thus, the rejection under 35 U.S.C. §102 has been overcome, and reconsideration is respectfully requested.

Claims 1-3, 13, 15-17 and 20 have been rejected as being obvious and unpatentable over Steinberger et al in view of the Chang U.S. Patent No. 5,254,671. The Examiner relied on Chang as disclosing various human IgG and variable regions of IgE Fab. The Examiner asserted it would have been obvious to substitute the variable regions of the IgE Fab as taught by Chang for the variable regions of the allergen specific human IgE Steinberger et al because Chang teaches that antibodies having human IgG1 or IgG3 are less immunogenic and can mediate antibody mediated cellular cytotoxicity or complement mediated cellular lysis to downregulate or lysis B cells expressing IgE.

However, Applicants submit that the Fabs, IgG, diagnostic reagents and vaccines defined by the present claims are nonobvious over and patentably distinguishable from Steinberger et al and Chang. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

The deficiencies of Steinberger et al are discussed above. Namely, Steinberger et al fail to disclose the claimed group 2 allergen specific human IgE Fabs. This deficiency is not resolved by Chang. That is, Applicants find no teaching or suggestion by Chang of the sequences of the present claims or of the claimed group 2 allergen specific human IgE Fabs. Accordingly, substitution of the variable regions of the IgE Fab as taught by Chang for the

variable regions of the allergen specific human IgE Steinberger et al as asserted by the Examiner does not result in or render obvious the presently claimed group 2 allergen specific human IgE Fabs or the presently claimed IgG, reagents and kits. Moreover, according to Chang, the disclosed antibodies are used to reduce or eliminate the B cells expressing IgE by antibody-dependent cellular cytotoxicity (ADCC), complement-mediated cytolysis, or other cytolytic or regulatory immune mechanisms (column 12, lines 46-50). In contrast, as described in the present specification beginning at page 3, line 9, the antibodies of the present invention suppress the degranulation of basophils and therefore no or little allergy-mediated substances are released. Applicants find no teaching or suggestion of such antibodies or activity by Chang or Steinberger et al.

In order to render a claimed invention obvious, the prior art must enable one skilled in the art to make and use the claimed invention, *Motorola, Inc. v. Interdigital Tech. Corp.*, 43 U.S.P.Q.2d 1481, 1489 (Fed. Cir. 1997). In view of the deficiencies of Steinberger et al and Chang, these references in combination do not enable one skilled in the art to make and use the claimed invention, and therefore do not render the claimed invention obvious. Thus, the rejection under 35 U.S.C. §103 has been overcome, and reconsideration is respectfully requested.

Claims 1, 2, 6, 7, 16 and 18 were rejected under 35 U.S.C. §103 as being obvious and unpatentable over Steinberger et al in view of the Frank et al U.S. Patent No. 5,945,294. The Examiner relied on Frank et al as teaching diagnostic kits for IgE detection using human Fc epsilon receptor. The Examiner asserted it would have been obvious to put an antibody as taught by Steinberger et al in a kit as taught by Frank et al for diagnostic assay.

However, Applicants submit that the Fabs, diagnostic reagents and kits defined by the present claims are nonobvious over and patentably distinguishable from Steinberger et al and

Frank et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

The deficiencies of Steinberger et al are discussed above. Namely, Steinberger et al fail to disclose the claimed group 2 allergen specific human IgE Fabs. This deficiency is not resolved by Frank et al. That is, Applicants find no teaching or suggestion by Frank et al of the sequences of the present claims or of the claimed group 2 allergen specific human IgE Fabs. Accordingly, putting an antibody as taught by Steinberger et al in a kit as taught by Frank et al for diagnostic assay does not result in or render obvious the presently claimed group 2 allergen specific human IgE Fabs, diagnostic reagents or kits. These references in combination do not enable one skilled in the art to make and use the claimed invention, and therefore do not render the claimed invention obvious, *Motorola, Inc. v. Interdigital Tech. Corp, supra*. Thus, the rejection under 35 U.S.C. §103 has been overcome, and reconsideration is respectfully requested.

Finally, claims 17-19 were rejected under 35 U.S.C. §103 as obvious and unpatentable over Steinberger et al in view of Chang and in view of Frank et al. The Examiner asserted it would have been obvious to put an allergen specific complete antibody such as human IgG comprising variable regions of the allergen specific human IgE as taught by Steinberger et al and Chang in a kit as taught by Frank et al.

However, Applicants submit that the diagnostic reagents and kits defined by the present claims are nonobvious over and patentably distinguishable from Steinberger et al, Chang and Frank et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

The deficiencies of Steinberger et al, Chang and Frank et al have been discussed above. Namely, each of these references fails to disclose the claimed group 2 allergen specific human IgE Fabs and IgG comprising the same. Accordingly, putting an antibody as

allegedly taught by Steinberger et al in combination with Chang in a kit as taught by Frank et al for diagnostic assay does not result in or render obvious the presently claimed group 2 allergen specific human IgE Fabs, diagnostic reagents or kits. These references in combination do not enable one skilled in the art to make and use the claimed invention, and therefore do not render the claimed invention obvious, *Motorola, Inc. v. Interdigital Tech. Corp, supra*. Thus, the rejection under 35 U.S.C. §103 has been overcome, and reconsideration is respectfully requested.

It is believed that the above represents a complete response to the objections and to the rejections under 35 U.S.C. §§ 102, 103 and 112, first paragraph, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,

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